

**REMARKS**

1. Introduction

Claims 20-33 are pending. Claims 20-33 are rejected. Claims 24, 28 and 30 are canceled. Claims 20, 23, 25 and 26 are amended herein. No new matter has been added as a result of the amendments

2. Response to Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 20-25 and 30 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants have amended claims 20, 23 and 25 in response to the indefiniteness rejection raised by the Examiner. Claims 24 and 30 have been canceled.

3. Response to Claim Rejections under 35 U.S.C. § 102(b)

Claims 26-27 and 30 are rejected under 35 U.S.C. § 102(b) as anticipated by Winquist '97. Without acquiescing to the propriety of the rejection, Applicants have amended claim 26. It is believed that the amendment to claim 26 renders the rejection under 35 U.S.C. § 102(b) moot.

Applicants have not addressed the rejection of claims 1, 4-7, 9-11, 14 and 16-17 under 35 U.S.C. § 102(b) as these claims were canceled in a previously submitted response and continue to remain canceled.

4. Response to Claim Rejections under 35 U.S.C. § 103

Claims 20-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Winquist '97 or Winquist '98 and further in view of Bouzid, Locatelli and Senda.

Applicants respectfully disagree with Examiner's analysis and respond as follows:

To establish a *prima facie* case of obviousness, **three basic criteria** must be met. First, there must be some suggestion or motivation, either in the references themselves or

in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s) when combined must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

**A Motivation to Combine Must Be Shown**

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). A mere conclusory statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). The Federal Circuit in *In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001), noted that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense' to one of ordinary skill in the art. *Id.* at 1697. In other words, *In re Zurko* expressly proscribes any reliance by an examiner on what constitutes the knowledge of one skilled in the art, when the assessment of that knowledge is not based on any evidence in the record. More recently, the Federal Circuit reiterated this position in *In re Lee*, where it took issue with the fact

that “neither the examiner nor the Board adequately supported the selection and combination of the ... references to render obvious that which [patentee] described.” *In re Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).

If a proposed modification would render the prior art teaching being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

**There Must Be a Reasonable Expectation of Success**

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986). Evidence showing that there is no reasonable expectation of success supports a finding of nonobviousness. *In re Rinehart*, 531 F.2d 1048 (C.C.P.A. 1976).

**All Claim Limitations Must Be Taught or Suggested**

To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). In other words, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382 (C.C.P.A. 1970). If an independent claim is non-obvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

The Examiner has not established a *prima facie* case of obviousness. The Examiner has failed to demonstrate any of the criteria required for a showing of *prima facie* obviousness, particularly, the requirements that there be a suggestion or motivation to modify the cited references or combine the reference teachings, and that all of the

claim limitations be taught or suggested by the prior art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

The claimed invention (as set forth in the amended claims) is drawn to a method of detecting the concentration of urea in a liquid. None of the cited references (Winquist '97, Winquist '98, Bouzid, Locatelli and Senda) either individually or in combination, teach the invention as claimed. As set forth in the previously submitted response, Winquist '97 and Winquist '98 **do not teach the quantitative analysis of urea** in a liquid. This **deficiency is not rectified** by Bouzid, Locatelli or Senda. **Therefore, the combination of the cited references do not teach or suggest all of the claim limitations** as required by *In re Royka*.

All claim limitations not taught

The arguments made of record in the previously submitted response with respect to the Winquist '97, Winquist '98, Bouzid and Locatelli references are not repeated herein. Examiner states in Item 5 of the office action that the newly cited Senda reference "clearly teaches the application of electrode sensors to the measurement of urea in body fluids." Contrary to Examiner assertions, the Senda reference reaches an amperometric ion sensor with a polarizable oil/water interface electrode for the detection of K and Na ions. There is no teaching in the Senda reference that the amperometric ion sensor with a polarizable oil/water interface electrode is also capable of measuring urea. Additionally, Applicants' invention is not directed to a polarizable oil/water interface electrode nor does Applicants' invention measure K and Na ions.

Secondly, Senda describes a “biosensor” for urea. Applicants’ invention is not a biosensor. One of ordinary skill in the art would recognize a biosensor as a device that uses a biological element, such as an immobilized enzyme or cell as a sensor.

Applicants’ invention does not employ a biosensor under any definition of the term. An Internet printout of several definitions for the term “biosensor” is attached hereto.

Examiner has incorrectly interpreted the meaning of the term “biosensor” to include all electrodes. Applicants’ invention does not utilize a biosensor which, as set forth in the attached print-out, is a specific term of art.

No motivation to combine

In addition, the Examiner has combined the Winkvist references with Bouzid, Locatelli and Senda references without making a showing of the requisite motivation to do so. Under the teachings of *In re Fine*, *In re Zurko* and *In re Lee*, mere conclusory assertions stating that the references relied upon teach all aspects of the claimed invention is not sufficient to establish a prima facie case of obviousness **without some objective reason to combine the teachings of the references**. It appears that Examiner has performed a word search on a publication database and cherry-picked references that share certain common terms with Applicants’ invention, but share nothing in common with respect to the substance of the invention. The presence of a few common terms in the cited references alone does not show that one of ordinary skill in the art would have been motivated to combine the cited references in order to arrive at the claimed invention.

Examiner has failed to adequately support the choice and combination of references that allegedly render Applicants’ invention obvious. This is clearly contrary to

the recent line of cases coming out of the Federal Circuit. It appears that the Examiner has employed impermissible hindsight reasoning and an “obvious to try” rationale to arrive at a finding of obviousness.

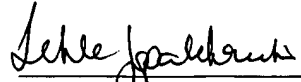
However, notwithstanding the improper combination of the references, Applicants respectfully submit that the combination of the Winkist references with Bouzid, Locatelli and Senda does not result in the claimed invention.

### **CONCLUSION**

In conjunction with the claim amendments and arguments set forth above, Applicants believe that they have addressed all of the Examiner's concerns and rejections. Applicants believe that the claims are now in condition for allowance and respectfully request that the Examiner grant such an action. If any questions or issues remain in the resolution of which the Examiner feels will be advanced by a conference with the Applicants' attorney, the Examiner is invited to contact the attorney at the number noted below.

No fees are due in connection with this response. If however any fees are due in connection with this paper, the Commissioner is hereby authorized to charge these fees and/ or credit any overpayment, to Deposit Account 10-0447 (Reference No. 45687-00082).

Respectfully submitted,

  
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Lekha Gopalakrishnan  
Reg. No. 46,733

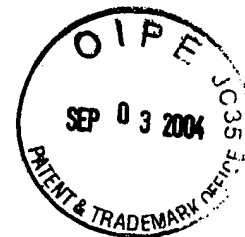
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Jenkins & Gilchrist, P.C.  
1445 Ross Avenue, Suite 3200  
Dallas, Texas 75202-2799  
(214) 965-7364 (Telephone)  
(214) 855-4300 (Fax)

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Web

Definitions of **Biosensor** on the Web:

A device that uses a biological element, such as an immobilized enzyme or cell, as a sensor.

[www.dddmag.com/scripts/glossary.asp](http://www.dddmag.com/scripts/glossary.asp)

A technology in which enzymes or antibodies are used to detect sugars and proteins in body fluids, contaminants in water and gases in air.

[www.biotech.ca/EN/what\\_glossary.html](http://www.biotech.ca/EN/what_glossary.html)

A sensor used to provide information about a life process.

[roland.lerc.nasa.gov/~dglover/dictionary/b.html](http://roland.lerc.nasa.gov/~dglover/dictionary/b.html)

Device in which powerful recognition systems of biological chemicals (enzymes, antibodies) are coupled to microelectronics to enable low-level detection of substances such as sugars and proteins in body fluids, pollutants in water and gases in air.

[www.biotechwithitaly.com/nw\\_glossary.html](http://www.biotechwithitaly.com/nw_glossary.html)

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